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NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE

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Commercial Applications and Economic Impact of Patented Animals

June 1988

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COMMERCIAL APPLICATIONS AND ECONOMIC IMPACT OF PATENTED ANIMALS

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TABLE OF CONTENTS

INTRODUCTION	1
OVERVIEW OF U.S. LIVESTOCK SECTOR	2
Beef cattle	2
Hogs	4
Sheep	5
Dairy	6
Broilers	7
Eggs	9
Overall conclusions	10
LABORATORY ANIMALS	11
POTENTIAL COMMERCIAL APPLICATIONS	12
Potential patentable developments	12
Structure of R&D activities	16
Incentive Issues	20
Examples of Applications	24
EXPECTED ECONOMIC IMPACTS	26
Impacts on inventors	26
Impacts on incentives	33
Impact on users (producers)	34
Impact on consumers	41
CONCLUSIONS	44
Economic considerations	44
Policy considerations	47
REFERENCES	49

LIST OF TABLES

1:	Beef cattle production and marketing arrangements	2
2:	Hog production and marketing arrangements	4
3:	Sheep production and marketing arrangements	5
4:	Dairy production and marketing arrangements	6
5:	Broiler production and marketing arrangements	8
6:	Egg production and marketing arrangements	9
7:	Major research activity on transgenic livestock, 1988	17
8:	Research funding for transgenic animal research	22
9:	Examples of potentially patentable transgenic animals	27
10:	Classification of animals by impacts of patents	35
11:	Impacts of biotechnology products on livestock production costs	37
12:	Economic relationships applying to the anticipated impacts of patents on livestock production	37

COMMERCIAL APPLICATIONS AND ECONOMIC IMPACT OF PATENTED ANIMALS

INTRODUCTION

On April 3, 1987, in Ex Parte Allen, the U.S. Patent and Trademark Office declared, "...nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter..." (Quigg news release). One year later the first patent for a higher animal was granted, in that case for a laboratory mouse susceptible to breast cancer. At the same time some 21 additional animal patent applications are said to be in process (Schneider, April 1988). These are believed to involve additional laboratory specimens as well as larger mammals for agricultural applications and, to a more limited degree, non-mammals.

This decision places the U.S. in a rare if not unique position internationally. Hungary does allow patents for animal breeds, but the system follows that for plant variety protection which is weaker than permitted for utility patents (see e.g. Williams; Lesser, 1986). The Soviet Union, too, grants a special form of protection for animal varieties (Straus; Bent, et al.). The differences in these laws along with fundamental valuation distinctions between centrally-controlled and market economics make the experiences in those countries not a good indication of impacts in the United States. The patent law in several major market economies, including Australia and Japan, does not specifically exclude animals as patentable subject matter, but the issue has yet to be acted upon despite the existence of several applicable patent applications (Van Horn, U.S. Patent and Trademark Office, personal communication).

With the current level of research activity and lack of precedent elsewhere, there has been considerable interest on the part of many, and concern among others, in the economic implications of patenting higher animals in the U.S. This paper is an attempt to assess the economic issues related to patenting higher animals, and in particular,

a) the economic implications for inventors, producers and consumers of patented animals, and

b) the ramifications of denying patents to this class of products.

Emphasis is placed on agricultural applications because of the large number of individuals who are affected directly and indirectly by the structure and profitability of the livestock sector.

OVERVIEW OF THE U.S. LIVESTOCK SECTOR

Livestock (including poultry) is the largest component of the U.S. agriculture sector, providing 53 percent of farm sales in 1982 and incorporating over two-thirds of total farm numbers including some in each of the 50 states (Census Agriculture, Summary and State Data, Table 2). The purpose of this section is to describe the structure and coordinating mechanisms within the large sector as a basis to understanding how patented animals could affect relationships horizontally among producers and vertically between suppliers and producers, and producers and buyers.

Based on the differences in the biology of the animals and the products produced, this large sector may be divided into seven major species/product classes as follows:

RED MEATS: beef cattle, hogs, sheep

DAIRY

POULTRY: eggs, broilers and turkeys

Each of these is discussed in order below with the exception of turkeys which, as a relatively smaller enterprise, are given less attention.

Beef Cattle

The beef cattle group is the largest and, due largely to the geographic division between the production of calves and finished (fattened) cattle, the most complex of the sub-sectors. Its salient characteristics are summarized in Table 1.

Table 1: Beef Cattle production and marketing arrangements

Components and Location

- Calf Production (cow-calf operations) - first 12-18 months of life on grasslands primarily in the Northern Plains, Texas-Oklahoma, and the Southeast.

- Cattle Feeding (feedlot operations) - done in feed-grain rich areas of the Western Corn Belt, the Texas High Plains, and Arizona-California.

- Breeding - produce primarily bulls for mating with some 50-70 active breeds. Artificial insemination use is very limited, 1-2%.

Size and Structure

- Calf Production - In 1982 there were 1 million farms with beef cows for a total herd size of 34.2 million. Most farms (60%) are very small, less than 20 cows. These are typically supplementary, part-time enterprises.

- Cattle Feeding - 27.7 million head were on feed on 250,000 farms in 1982. Of these, 95% fed less than 200 annually but contributed only 18% of total supplies. A quarter of all fed cattle comes from lots with one-time capacities of 32,000. Growth of the largest size category suggests substantial size economics, but these are not well documented. About 50% of all beef cattle are grain fed.

- Breeding Sector - numerous small operators - numbers are in the tens of thousands - produce purebred bulls of individual breeds. Reproduction is at the level of one calf per year.

Exchange Arrangements

- Breeder - Cow-Calf - bulls are sold outright, based on performance trials, to local cow-calf operators at a rate of about 1:25 cows.

- Cow-Calf to Feeder - typically sales are made outright, but due to geographical separation often a commission agent (order buyer) handles the animals. Federal grades exist but are not extensively used. Typically a calf will change ownership several times.

- Feeder to Packer - 80% of sales are direct (private treaty) sales; the remainder move through auction and terminal markets. Private treaty pricing is generally keyed to the Chicago futures price or other reported price. About 5 percent of cattle are fed on a service fee basis (custom feeding), typically for larger packing companies.

  The beef packing sector is becoming more concentrated with a 1987 four-time concentration level of 64%, or 82% for boxed beef (carcass sections packed in poly bags) only.

Selected References

- Data - USDA Situation and Outlook; USDA, P&SA Resume; Census of Agriculture; Census of Manufacturers; U.S. Dept. Agr., Livestock and Meat Stat.

- Books and Articles - Stillman, Weimar and Duewer; Beale, et al.; McCoy; Rhodes, et al.; Ward 1987; Nelson; Schnittker Assn.; Quail; Hayenga, Dieter and Montoya; Boykin, Gilliam and Gustafson; Gilliam 1985; Gilliam 1984; Petritz, Erickson and Armstrong; OTA 1986; Ward 1982; Acker

Overall, the beef cattle sector is characterized by its huge size. This, however, is somewhat misleading as a small proportion of feed lots provides the bulk of beef. Cow-calf producers are numerous and decentralized, making coordination and standardization difficult. The packing sector is growing in concentration raising concerns among some economists for the future, but present conditions are not problematic.

Beef cattle are unique for the number of exchanges and distance calves

travel. This system is based on sound cost considerations, but does make the preservation of individual animal identity very difficult.

Hogs

Hog production has been undergoing a transition in the past decade or so. From a time when it was intermittent and supplemental to grain production (hogs are not ruminants and require high energy diets) - really an alternative means of selling grain - it has been shifting to specialized, enclosed "confinement" systems where production is continuous. Table 2 is a synopsis of the major attributes of the sub-sector.

Table 2: Hog production and marketing arrangements

Components and Location

- Farrow-to-finish operations - incorporating breeding, pig production and fattening within one farm, accounts for three-fourths of production. Separate feeder pig and finishing operations make up the last 25% of output. Production is concentrated in the grain-rich North Central and South East regions.

- Breeding - purebred breeding boars are produced by numerous small operations; crossbred animals by a small corporate sector. Artificial insemination use is but 1%. Eight breeds dominate.

Size and Structure

- Farrow-to-finish - the USDA estimates a 1988 herd size of 53.8 million head, enough to provide 62 pounds per capita (carcass weight).
  In 1982, 315,000 farms were listed as producing hogs. The smallest 90% producing 1,000 head annually or less provided 50% of total output. Farm numbers in this size category are down by 80% over 1950-80. The largest size category, over 5,000 head, accounted for 1% farm numbers but 12% of output. This segment, which is often affiliated with a commercial enterprise like feed milling, displays significant size economies up to 250,000 head annually.

- Breeding sector - purebred producers selling principally to small producers are large in number - over 10,000. Crossbred operations are small in number (four firms have an 85% share of the corporate market) but more sophisticated and often affiliated with a large parent company like Monsanto or Ralston Purina. Recently some are moving into the purebred market. Sows can litter twice a year producing 16-20 pigs annually.

Exchange Arrangements

- Breeder-Producer - breeding stock is sold outright, small operators often using state university boar testing programs to evaluate animals.

- Feeder Pigs - Feeder-pigs are sold outright, often in local auction markets or by producer cooperatives, and identity is lost. This exchange is internalized by farrow-to-finish operations.

- Feeder-Packer - some 90% of market hogs are sold direct to packers using negotiated prices. The remainder move through auction and terminal markets. Typically a packer will have a proprietary grading system rather than use the official USDA one.

  Concentration in pork packing is estimated at a modest 37 percent share for the four largest. Increases are predicted but not, for several technical and marketing reasons, to the degree of beef.

Selected References

- Data - as with beef in Table 1

- Books and articles - Stillman, Weimar and Duewer; Van Arsdall and Nelson 1984; Van Arsdall and Nelson 1985; McCoy; Ward 1987; Connor, et al.; Van Arsdall and Gilliam; Hayenga, et al.

Significant concentration of production has occurred over the past decade and is expected to continue into the future. Yet size economies are such that it need not reach critical proportions. The boar breeding sector, too, is increasing in concentration and many of the small purebred operations can be expected to exit when the few corporate breeders target that market. The connection of large farrow-to-finish operations and corporate breeders with each other and with large, cash rich firms means that the hog industry will develop differently from many other livestock sectors.

Sheep

Sheep constitute a relatively small and declining sector among the red meats with numbers down from 50 to 10 million over 1945-85. Imports have made up a small part of the decline, constituting 10 percent of consumption in 1985. The sector overview is contained in Table 3. This sub-sector is not as well documented as those for cattle and hogs.

Table 3: Sheep production and marketing arrangements

Components and Location

- Fed Lamb - started on pasture and transferred to feed for finishing. Production is concentrated in the South and West.

- Spring Lamb - milk fed to light weights. Volumes are low.

Size and Structure

- Fed Lamb - of the 100,000 farms in 1982 with sheep, 50% had less than 50 head. Total 1982 herd size was 12.4 million head.

- Breeding - this is a small-scale enterprise with some 25,000 firms involved, many small, part-time or hobby-type operations. Several universities sell purebreds; 12 breeds dominate in the U.S.

Exchange Arrangements

- Feeder Sheep - Feeders - little is documented on this segment of the sector.

- Feeders-Packers - nearly 85 percent are sold direct to packers. A relatively large portion (27%) is fed by or for packers (custom feeding). In the mid 1980's, only 14 larger sheep packing plants were recorded, but no competitive problems have been detected.

Selected References

- Data - see Table 1

- Books and Articles - USDA, P&SA 1987; Stillman, Weimer and Duewer; Campbell and Lasley

With a declining number of head, of producers, and of active research interest, the sheep sector is more vulnerable to non-competitive conditions than are the other red meats. New management systems under development hold the promise of improved profitability, but their success in the field is as yet unproven (Hogue).

Dairy

The dairy sector is fundamentally different from red meats due to importance of the Federal milk marketing order system (see eg. Babb, et al.). Production efficiency has been growing steadily so that half the cows are needed to produce the same volume of milk as 20 years ago. This sub-sector is summarized in Table 4.

Table 4: Dairy production and marketing arrangements

Components and Location

- Milk Production - virtually all dairy operations produce their own replacement cows. Production occurs in all states, due in part to Federal pricing systems . However, California, Minnesota, New York and Wisconsin are the leading producers.

Milk is the principal product. By-products of dairying are cull cows for slaughter and bull (bob) calves for veal. Some 20-25% of cows are registered purebreds.

- Breeding - about half of breeding is done with artificial insemination. Bulls for natural breeding are purchased locally. Cows must calve annually. One breed, Holstein-Friesian, constitutes 90% of the dairy sector.

Size and Structure

- Milk Production - most dairy farms are small (40-100 head) family operations producing most of their own feed. Some "dry lot" operations mostly in California milk more than 1,000 cows. Recent Federal policy to reduce support payments have led to reductions in the dairy herd. Over 120,000 commercial-sized farms were reported in 1983.

- Breeding - the domestic semen-producing sector is dominated by four firms, two of which are cooperatives and one is owned by W.R. Grace Co. Breeding bulls are produced by 20% of the registered herd operations which make 50% or more of income by selling breeding stock.

Exchange Arrangements

- Milk - prices are determined by Federal policy with producers in an order area receiving an average (blend) price for fluid (higher value) and manufacturing milk. Cooperatives play a major role in handling milk and some further processing.

- Surplus stock - most dairymen ship cull cows and calves to local auction and terminal markets for sale.

Selected References

- Data - in addition to the sources in Table 1, the USDA produces extensive statistics on milk production and prices.

- Books and Articles - Babb, et al.; OTA, 1986;

The role of Federal milk market order pricing combined with the large number of cooperatives virtually assures pricing equity. (Some economists believe large dairy cooperatives have received excessive prices - see Eisenstat, Masson and Roddy). The sector is dominated by small family operations, but farm size is continuing to increase.

Broilers

Broiler chickens are virtually a new agricultural product in the post World War II period. New breeds and management techniques made it possible to

produce chickens rapidly and economically. Presently chicken consumption is second only to beef and may surpass it this century. This sub-sector is organized somewhat differently from the red meats, as is described in Table 5.

Table 5: Broiler production and marketing arrangements

Components and Location

- Broiler Production - larger operations combine hatching operations (chick production) and feeding, bringing birds to market in 7 weeks. Production is heavily concentrated in the Southeast and South Central areas where mild temperatures and abundant feed are available.

- Breeding - breeders produce "parent" or "grandparent" stock for use in the production of commercial chicks.

Size and Structure

- Broiler production - in 1982 nearly 53,000 farms reported meat-type chicken production, but an estimated one-third of that number produced 80% of the output. Farms with 100,000 plus birds are no longer uncommon.

- Breeders - concentration in this sector is very high. Three firms control 90% of the female market while four firms have the same share in the male market. Entry barriers are high. Commercial birds are crosses of the four dominant breeds.

Exchange Arrangements

- Producer-Processor - broiler production is distinct in that the producer does not own the birds. They are owned by an "integrator" who pays the grower on some formula basis keyed to weight gain. Concentration among integrators is high with some 11 firms dominating the sector. They are often affiliated with a feed processor or other commercial entity. Product differentiation is increasing with the activities of Perdue Farms and Holly Farms. There is essentially no live bird market; meat prices are typically keyed to (formula priced) USDA reported prices. Integrators typically own, or contract with, processors and production is within a limited range of the plant.

- Breeding Stock - breeding birds are sold to integrators who supply their contract growers.

Selected References

- Data - references listed in Table 1

- Books and Articles - Marion and Arthur; Stillman, Weimar and Duewer; Marion; Lasley, F.A.; Campbell and Lasley

The broiler sub-sector has posted excellent efficiency gains over the past 20 years. The relatively few number of integrators raises questions about the competitive nature of the sector, but performance to date has been good, possibly because of competition from large supermarket buyers. This may change as brand names become more established. The breeding sector is more problematic with high concentration and entry barriers, but firms must compete based on the productivity of their products.

Eggs

Egg production is a traditional but declining enterprise as per capita consumption has fallen from 320 to 250 over the past quarter-century. This has put tremendous cost pressures on the sub-sector. Activities of egg production are summarized in Table 6.

Table 6: Egg production and marketing arrangements

Components and Location

- Egg Production - large operators hatch their own replacement hens and sell eggs. Production is concentrated in the Southeast, South Central and North Central regions.

- Breeders - breeders produce parent stock for sale to commercial producers. Four standard breeds dominate.

Size and Structure

- Egg Production - Defining commercial producers as those with more than .5 million birds, there were between 6-9,000 in 1982. This is less than 4% of total farms producing eggs. A few firms are enormous with some 5 million birds in production. An estimated 37% of eggs are produced by large producer/processors, 43% under contract with integrators, and 20% by other commercial farms.

- Breeders - an estimated five breeders dominate 80 to 90% of the domestic pullet market.

Exchange Arrangements

- Egg Production - virtually all eggs are priced according to two reported prices, the USDA Market News (west of the Rocky Mountains) and Urner-Barry (remainder of the country). There have been several evaluations of these prices, but no major limitations have been detected. Individual buyers negotiate premiums/discounts around these prices.

- Breeding Stock - breed animals are sold directly to larger operators.

Selected References

- Data - refer to Table 1
- Books and Articles - Stillman, Weimar and Duewer; Marion; Lesser and Warman; Acker

Declining consumption along with the appearance of substantial size economies have led, and are likely to continue to lead, to further concentration in egg production. The severely depressed earnings, nonetheless, suggest strongly that the sector is operating competitively. More problematic on an industry structure basis is the breeder sector, but studies have shown that the price of agriculture inputs is affected by the profitability of the sector. In such a case it might be imagined that breeder prices are not uncompetitive.

Overall Conclusions

The significant overall attribute of the U.S. livestock and poultry sector is the interrelated characteristic of its enormous size and geographic/enterprise diversity, coupled with organizational differences among the individual sub-sectors (broiler chickens, beef, pork, etc.). This characteristic means coordination of activity both vertically and horizontally in the system is a major issue that effects, among other matters, the introduction of new technology such as patented animals. Presently, much of the coordination is achieved through prices (market activity) although contracting is taking on an increasing role. The major exception is broilers for which virtually the entire output is produced under contract. Of particular importance to patented animals is the matter of maintaining identification and control over products with no obvious distinguishing characteristics and that frequently pass through multiple ownership exchanges. Beef cattle are the most extreme example of such diversity of ownership.

By all indications, the livestock production and processing sector is in the main a highly competitive one. A possible exception is the poultry breeding sector; beef packing has been moving toward a less competitive structure but does not appear to have reached that level at present.

LABORATORY ANIMALS

Laboratory animals, as they affect the issues under consideration here, are the specialized lines used as models for understanding diseases and their cure. The animals in use typically have one or several specialized characteristics, as follows:

* pure lines which have known and stable attributes and are hence useful in controlling for random genetic factors in research, and

* strains, usually derived from a naturally occurring mutants, bred to have an inherited genetic malfunction causing a particular disease to recur. Examples of such disease models are dwarf mice, mice which destroy the insulin producing tissues in a manner similar to juvenile diabetes in humans, a canine model with muscular dystrophy, a hairless rat used for dermatological studies, and an immunologically-deficient (nude) mouse for cancer research (Prof. Quimby, Veterinary College, Cornell Univ., personal communication).

Numerous disease models of this type exist and are in regular use in the major medical and veterinary research institutions across the country and in other parts of the world. The major source of these animals is the Jackson Laboratory of Mt. Desert Island, Maine which owns and sells by far the world's largest collection of mutant animal lines. This is a for-profit company from which animals are purchased, but there are no royalty arrangements nor restrictions on the buyer breeding replacements from the purchased stock. Other for-profit companies in the business are the Charler River Breeding Laboratory (Boston Mass. area) and the Institute for Cancer Research (Elkens Grove, Penn.).

A secondary source is the large number of research institutions which own a few individual models, as Cornell Univ. owns the dog strain with muscular dystrophy. Typically these animals are given without charge to other researchers as supplies become available (Prof. Quimby, Veterinary College, Cornell Univ., personal communication).

Clearly, the supply of these unique animals is tightly controlled, as would be expected with such specialized products and markets. However as long as the animals are self-reproducible and reproductive rights for the purchaser are not restricted, each customer becomes in effect a competitor. In this way, reasonable competition can be maintained despite the solitary supplier of many strains.

POTENTIAL COMMERCIAL APPLICATIONS

A clear indication of potentially patentable inventions in the sphere of higher animals is the 21 patents applications presently on file with the Patent Office, but beyond the single patent already granted that information is confidential (Schneider, April 1988). As an alternative to delimiting the product scope of potentially commercial developments in the area of higher patented animals, it is helpful to examine the patentability requirements for indications of what likely will, and will not, be patentable.

Potential Patentable Developments

Potentially patentable animals would seem to be derivable from one of four sources: 1) naturally occurring, 2) products of "traditional" breeding, 3) products of genetic engineering, and 4) other, such as the polyploid oyster which is the subject of Ex parte Allen. These are examined in turn below.

NATURALLY OCCURRING ANIMALS: Naturally occurring organisms are unlikely to be patented "...unless given a new form, quality, properties or combination not present in the original article existing in nature..." (Quigg letter). As Tegtmeyer notes (testimony,p.11), "A naturally occurring article, that is substantially unaltered, is not a 'manufacture'". One accepted means of creating a manufacture from a naturally occurring product is to purify it (Van Horn). That approach has been followed for microorganisms, but its application to higher animals is unclear unless it consisted of some breeding procedure to stabilize the trait.

Take, for example, a shrimp (the case cited by Tegtmeyer). A wild example which happened to be blue would most probably not be patentable. If it were bred skillfully so that the blueness trait were passed on in a stable manner, then that strain may be patentable as a "purified" version. However, the scope of protection would likely be very narrow if no causality for blueness were presented. The patent would essentially cover only that strain, leaving outside the patent scope alternative means of achieving blueness (Van Horn, Patent and Trademark Office, personal communication). This is essentially the situation under Plant Patents which contributes to the limited scope of protection for those products (see discussion in Neagley, Jeffrey and Diepenbrock). The situation could be different if the unique trait were difficult to identify. Suppose a technician realized from an examination of

the shrimp gills that they were similar to brine shrimp, which are tolerant to high salinity. A stable line of salt-tolerant shrimp could well be patentable as the process for detecting the novel attribute would not be obvious. The strain would, however, suffer from a limited scope of protection as discussed above.

TRADITIONAL BREEDING: Another source of novelty is "traditional" selective breeding practices. Selective breeding is, however, slow. One source of slowness is the inherent limit to change which can be made through selective breeding. Campbell and Lasley (p. 172-73). summarize this concept in the formula:

$$\text{Annual genetic prog.} = \frac{\text{selection diff. x trait heritability}}{\text{generation interval (yrs.)}}$$

Campbell and Lasley give an example for beef feeder calves showing the annual genetic progress under the assumed conditions is 3 to 4.6 pounds (less than 1%). For the patent system this slow progress is important because each cross may be so little differentiated from its predecessors as to be potentially "obvious", which is to say excluded from patenting. There is, however, nothing inherent about traditional breeding practices which would preclude patenting of the products. This point was expressed in Re Merat (Court of Customs and Patent Appeals, 1975) in which the developer of a dwarf chicken variety was denied a patent based principally on the failure to reveal a method for reproducing the variety. (The examiner raised the matter that animals were not then patentable subject matter, but the Court of Appeals did not consider that issue.) Thus, the application was not rejected because of the form of the invention. But the practical realities of traditional breeding practices are that they are unlikely to be a major source of patentable inventions.

GENETICALLY ENGINEERED ANIMALS: The principal source of patented animals is anticipated to be those created through gene transfers (recombinant DNA or rDNA; see Lasley, J., Chap. 3; Watson, Tooze and Zurtz, Chap. 14 and 16; Office Technology Ass. 1988). Such animals will begin with a novel gene, or genes. These genes may come from another species, from a natural mutant, from an induced mutant such as caused by irridation or some other means of

producing a "designer gene". These genes must be identified as to function, isolated and removed from the DNA strand using the appropriate restrictive enzyme, stabilized and cloned, and finally inserted into the DNA of the target species using microinjection or other procedure.

Gene transfer is made simpler by the fact that function is not location specific, although the efficiency, stability and inheritability of the gene may be location-sensitive (Gordon, et al.).

Two factors, nonetheless, complicate and limit the practice. First, complex attributes like milk production are controlled by multiple genes, often by interacting with each other in ways not currently well understood. As a result, it will be some time into the future before sufficient knowledge exists to permit the development of animals with complex traits (OTA 1988). But even then the procedure will be limited by the amount of genetic material which can be successfully transferred, at least using current procedures. If a typical mammalian genome weighs on the order of $3X10^6$ kilobases, the size of the fragment transferred using microinjection typically ranges from 5 to 10 kilobases or much less than one percent of the mass (Dr. Noden, Biotechnology Inst., Cornell Univ., personal communication). The well known Hammer et al. study of transgenic sheep, rabbits and pigs, for example, used a 2.6 kilobase linear fragment of the genome (p.681). Work on a gene transfer technology using retroviruses suggests a similar limit to the amount of genetic material which can be transferred. Thus, for the foreseeable future at least, the genetic change in animals which can be caused by transgenic procedures is strictly limited.

The second factor is the regulation of the transplanted gene. The output of the structural genes are regulated by an additional gene or genes known variously as control, regulator, or promoter genes. The need to include these genes not only complicates the identification and transferral but also further limits the number of traits that can be added to an animal. The control of gene expression is seen as one of the fundamental complexities of transgenic animals (Dr. Pursel, USDA, Ag. Res. Service, Reproduction Lab., personal communication; Habers, et al.).

In higher animals the DNA in germ-line cells (egg and sperm) is potentially integrated into the chromosome. The altered DNA is microinjected into the fertilized egg and inserted into a host mother, or cultured and divided into clones, and then inserted. Watson, Tooze and Kurtz (p. 200)

estimate the efficiency for this process for mice to range from a few to 40 percent with an estimated overall value of 10 percent. For higher animals the success rate to date has been far lower, on order of .2 percent (Wall, USDA, Ag. Res. Service, Reproduction Lab., personal communication).

Pursel (USDA,Ag. Res. Service, Reproduction Lab., personal communication) offers a more detailed breakdown. Among larger animals the success of microinjection is on the order of .5 to 1% of injected eggs result in live births. Among the births about half carry the altered gene, of which some one-third are so-called mosaics meaning the gene is not present in all cells and the animal may or may not express the desired trait and pass along the trait to progeny (see also Stewart, Wagner and Mintz, p. 1047). These factors lead to the exceptionally low overall success rate. Mice have proven more tractable with live births on the order of 3 to 6 percent. Due to the inefficiency of microinjection other transfer procedures are under study, including retroviral processes, but that technique at best can handle only a very limited size piece of DNA.

For patent issues the success rate is significant as it applies to the disclosure requirement. An invention to be patentable must be described "... in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same..." (35 USC sec 112). For biological materials which, at the judgment of the Patent Office examiner, cannot otherwise meet this requirement, a sample deposit is required. One failure to meet the requirement is characterized by the need for undue experimentation to recreate the invention (Van Horn). The factors considered in determining undue experimentation were set out in a case applying to bacteria in Ex parte Forman (230 USPQ 546 (Board App. 1986)).

The same disclosure requirements apply to higher animals as well, but in a new PTO rule 1.200 now under study it is implied that undue experimentation will not be involved; "...it is anticipated that inventions relating to the development of animals having new and otherwise patentable characteristics will rely on the identification and description of a known and readily available animal that will be treated in a reproducible process to obtain the new animal variety." (PTO "Note"). Whether the low success rate with larger animals will affect this decision on the requirement of a deposit is not known at this time. Should deposits be required, they will introduce an additional cost for the inventor and complexity, but there is no indication that such a

requirement would preclude patents for technical reasons. Rather, it seems likely frozen embryos will be used as the deposit form. Frozen embryos have been shown to be viable for at least ten years (Prof. Foote, Animal Sci., Cornell Univ, personal communication).

OTHER: The "other" category of sources of patentable animals is so large and potentially rich as to defy treatment here. It includes such developments as the polypoid oyster of Ex parte Allen (e.g., extra sets of chromosomes and sterility by applying hydrostatic pressure). Developments in this category are likely to be created through some describable process, not require a deposit, and probably not to be self-reproducing. As such they are in a very different technical category from those inventions generated through genetic engineering.

Structure of R&D Activities

Research leading to transgenic animals is quite recent with the significant reports of research achievements dating to only the early 1980's. Despite that fact, the present level of scientific research and dollars expended on research leading to disease models among laboratory animals is already substantial in the U.S. and abroad. The list includes numerous research institutes (eg., National Cancer Institute; Mark, Sharp and Dome Research Lab) and universities (eg. Harvard, Yale, Ohio State) and is too extensive to repeat here (but see literature overview below).

LIVESTOCK RESEARCH: Livestock researchers concentrating on transgenic applications to livestock are fewer in number and can be identified with a reasonable degree of completeness Table 7. This table is not intended to be exhaustive, nor is the order of entries intended to convey anything about the relative prominence of the research activities.

In addition to what is described in the table, researchers are active in these areas in Holland, France and Ireland. The level of work in Japan is particularly large.

Private firm activity in the U.S. is difficult to characterize due to its proprietary nature. Larger firms rather than supporting major in-house research programs appear to be contributing to university programs. But, in general, the view of U.S. private enterprise is to leave the background work

Table 7: Major research activity on transgenic livestock, 1988

Name of Firm or Institution	Key Personnel	Areas of Research
A: U.S. Public (Federal, state and university research)		
1. USDA, Ag. Res. Service Reproduction Laboratory Beltsville, MD	Drs. Purcell and Wall	growth hormones in swine, regulators and related factors
2. Ohio University Edison Animal Biotechnology Center Athens, OH	Prof. Wagner	as above
3. Tufts University Veterinary College Cambridge, MA	Prof. Ebert	poultry retroviruses
4. USDA, Ag. Res. Service Poultry Laboratory East Lansing, MI	Dr. Crittenden	as above and disease resistance
5. University of Wisconsin Dept. of Animal Science Madison, WI	Prof. First	growth hormones in cattle; retrovirus vectors for cattle and swine
6. NC State University Dept. of Animal Science Blacksburg, VA	Prof. Petters	poultry and swine retroviruses (principal effort on procedure)
7. University of Missouri Dept. of Animal Science Columbia, MO	Prof. Pinkert	immunoglobins in swine
8. University of California - Davis Davis, CA	Prof. Anderson Animal Science Prof. Osborne - Vet. College	disease resistance
9. Cornell University Dept. of Animal Science Ithaca, NY	Prof. Foote	embryo cloning and transplants
10. Texas A&M University Dept. of Animal Science College Station, TX	Prof. Kramer	believed to have no current projects
11. National Institutes of Health Bethesda, MD	Dr. Anderson	

Table 7. cont.

12. Salk Institute La Jolla, CA	Dr. Vale	growth hormones
B. Private Firms in US		
1. Granada Corp. Houston, TX	Dr. Massey	emphasis on gene transfer techniques; embryo transplant
2. Clontech Labs Palo Alto, CA	Dr. Fong	laboratory animals
3. Transgenetics, Inc. Worchester, MA		
4. Gentech South San Francisco, CA	Dr. Stewart	contributed to development of patented mouse strain
	Drs. Tam and Mason	----------
5. Cetus Emeryville, CA	Dr. White	----------
6. Monsanto Chesterfield, MO	Dr. Baile	----------
C. International Efforts		
1. Univ. Adelaide Adelaide, Australia	Profs. Seamark and Wells	growth hormone in hogs
2. Commonwealth Scientific and Industrial Research Organization Sidney, Australia	Dr. Ward	growth hormone in sheep
3. Marine Research Institute Nagasaki, Japan	----------	growth hormone in flounder

Table 7. cont.

4. ---------- Edinburgh, Scotland	----------	transgenic sheep producing human Factor IX (blood clotting protein) and alpha 1 antitrypsin in the milk
D. Private Firms - non-US		
1. Animal Biotechnology Cambridge Cambridge, UK	----------	breed improvement in cattle and swine
2. Trangenetic Sciences UK	----------	disease resistance in poultry
3. Hayashibara Biochemical Labs Japan	----------	alpha interferon in transgenetic hamsters

Sources of Information:
Dr. Purcel, USDA, Ag. Res. Service, Reproduction Lab, personal communication.
Dr. Hardy, Pres., Boyce Thompson Institute, Ithaca, NY, personal communication.
Mr. Duffey, General Patent Counsel, Monsanto Co., St. Louis, MO, personal communication.
Dr. Hansel, Veterinary College, Cornell University, personal communication.
Publications: Miller, p.7, Duffey, Genetic Engineering News, April 1988.

to the universities until it moves closer to the commercialization stage (Dr. Brill, VP, Agracetus, Middleton, WI, personal communication). Many of the foreign "private" firms were created by the government as a means of commercializing state-supported research.

RESEARCH FUNDING: A major source of research support for experimentation on laboratory animals is the National Institutes of Health (NIH). The NIH has a large external research budget of about $6 billion annually. Of this some 45 percent support research of which disease models and other laboratory animals would be included, but Dr. Gay, director of the Animal Resources Program of the NIH estimates the transgenic component to be no more that a "few million" (personal communication) (Table 8). Recent changes in reporting procedures have made it virtually impossible to determine the proportion of projects, typically classified on a disease basis, would be spent on transgenic animal research.

Research funding for agricultural animals is quite limited (Table 8). The gross estimate in this area is around $15 million annually, but only a portion of that amount would be spent on transgenic research. Dr. Hardy, President of the Boyce Thompson Institute, a leading research institution employing biotechnology processes, estimates that $25 million in public funds is spent in this area annually (the same level of funding he estimates from private sources) (personal communication). His estimate probably includes some funding for small animals research with applications to larger animals.

Incentive Issues

Patents are an economic instrument, the granting to inventors for a limited time the "exclusive rights to their ... discoveries" for the purpose of "promot[ing] the progress of science and the useful arts", as it is stated in the Constitution (Art. 1, Sec. 8). Economic incentives are not difficult to structure; the complexity is providing enough but not too much incentive. In Jefferson's words, the patent system strives to encourage the development of "... those inventions which would not be disclosed or devised but for the inducement of the patent." (quoted in Graxam v. John Deer Co., 383 US 1,p.9).

To explore this concept further it is helpful to subdivide the inventive process. Using the terms of the economist, not the patent attorney, the "invention" process consists of three distinct stages. The invention itself

is the creative idea, the first indication the idea will work. Following are two key steps, **innovation**(development) and **diffusion**. Innovation is the process of investing in the invention to make it practical and commercializable, what is known in patent terms as reduction to practice. This is the stage at which the major expenditures are made. Finally, diffusion involves the marketing of the invention, including any further modification to make it commercially viable (see eg., Scherer, Chap. 16).

Patents are focused on providing incentives at the innovation stage, for studies have shown the inventive process is induced by a range of factors among which the profit incentive is not necessarily large (Jewkes, Sawers and Stillerman). Incentives for investment in innovation come from two sources, protection from direct copying and freedom to sell or license the invention. The cases in which incentives have been found most effective are 1) when the invention is very major **if it works** but has a large risk of commercial failure, and 2) the common, small improvements which require a large market and/or long time period to recover the investment. Innovation in the area of patented animals would seem to fit both of these cases, some very major but highly uncertain developments and a large number of minor enhancements.

Thus, on purely **a priori** grounds based on past experiences, animal patents might be expected to increase private investment in innovation research. Documenting that patents have indeed spurred research expenditures has, however, eluded economic analysis, at least until recently. (But for a theoretical treatment of "optimal" patent protection see DeBrock). What has changed is the passage of the Plant Variety Protection Act. The PVPA provides some additional insight into the response to the patent incentive because it provides a point in time when protection became available. Thus, if it can be accepted that investment in plant breeding following the passage of the PVPA are <u>caused</u> by the Act, and not merely temporally associated with it, then the incentive effect of patents can be placed in sharper focus.

PRIVATE RESEARCH UNDER THE PVPA: Three notable studies of the PVPA have been completed over the past decade. All indicate that prior to this Act, investment in sexually propagated, non-hybrid seeds was done at public expense due to the inability of private firms to recover breeding research expenditures.

Table 8: Research funding for transgenic animal research

Source	Amount and Period	Source of Information	Comments
LIVESTOCK			
USDA, Ag. Res. Service	FY'88 - $9.3 Million	USDA, ARS	Funding for USDA research $5M in monoclonal antibody and other research excluded
USDA Competitive Grants	FY'86 $6.6M total Animal Growth and Development Animal Molecular Biology	USDA, Coop State Res. Service (a)	Estimate that 10%, and no more than 20%, of these funds will lead to patentable animals
State Ag. Exp. Station Research	FY'86 $.5M Problem 311: Imp. Biological Efficiency in Production of Livestock, Poultry, etc. and Problem 310: Reproductive Performance of Livestock, Poultry, etc.	USDA, Coop State Res. Service (b), Table II-D and II-B	A total of $6.5 million were dispersed for commodity work on livestock and poultry
LABORATORY ANIMALS			
National Institutes of Health	FY'88 - est. few million	Dr. Gay, Director Animal Resources Program	Small fractions of the $2.7 billion allocated externally for disease-specific research

The most thorough study was done by Butler and Marion for the U.S. Department of Agriculture and included a survey of private seed companies. The following conclusions were drawn (pp. 30, 32, 38-39):

1) there is a reasonable probability that the PVPA has had some influence on plant breeding R&D activity in the private sector.

2) a large number of companies initiated plant breeding programs during the late 1960's and 1970's

3) the number of soybean and wheat varieties released during the 1970's increased rather sharply.

Brim documented a dramatic rise in the number of private soybean researchers in the wake of the PVPA, from two in 1966 to six in 1971 to 63 in 1984 (Brim, Table 3). Moreover, the acreage share of private soybean cultivators grew from 15 percent in 1977 to close to half (46%) in 1986 (Brim, Table 5). In light of the estimated $600,000 cost of developing a new soybean variety, Brim associates these changes with the incentive effect of the PVPA. Finally, Perrin, Hunnings and Ihney ran a more recent survey of privets plant breeders covering the period 1960-79. They concluded (p. 27) that "... there seems to be little doubt that private research on soybeans and cereals was affected positively by the PVPA." This result is evident in terms of both programs and expenditures.

Moreover, they found there was an upward trend in soybean yields following the passage of the PVPA which is consistent with an hypothesis that these varieties are more productive than the products of public breeding (p. 36). As such, it provides some counter evidence to charges that private varieties are bought only because of heavy promotion (see eg., Stallman and Schmid, p.435). The results are not statistically significant at commonly accepted levels, but the test is such as to average the impact of all varieties planted, including those held over by farmers from previous years.

PUBLIC RESEARCH UNDER THE PVPA: The net impact of this Act depends on its impact on public investment as well. If public investment in plant breeding declined sharply following the passage of the PVPA, then the net impact on overall breeding research would obviously be smaller. Furthermore, the important role of the public breeding as a market competitor would be diminished (Butler and Marion, p. 78). Indications, nonetheless, are that the

passage of the Act did not diminish public involvement. Butler and Marion surveyed Agricultural Experiment Station directors and public plant breeders and found the great majority (at least three quarters) felt the Act had no impact on funding or the direction (applied vs. basic) research (p. 40).

This evidence is supplemented with some that the public sector is itself using the PVPA to generate funds it support its own breeding programs (see Lesser, 1987 (b)). Outside the US, the experience in the UK was that the adoption of Plant Breeders' Rights led to a substantial increase in both private and public breeding (Cooper, pp. 76-77).

Summary

The best available information then suggests strongly the ability to patent animals will spur investment in related innovation research. Certainly that has been the experience under the PVPA despite its weaker protection, and it may be expected that same effect would apply to animal research although the result cannot be predicted with certainty. Moreover, there is no obvious decline in public expenditures on this form of research following the allowance of patents, but that is a policy decision which cannot be forecast with certainty either. What does seem certain is that any innovation research will not be spread evenly but rather will be concentrated on specific species and products according to market opportunities and scientific constraints.

Examples of Applications

There are a reasonable number of potentially patentable developments in the area of transgenic animals which have been described in the biotechnology literature and are known to fellow researchers. A sample list is included in Table 9 to give an indication of the thrust of current research. The number of examples per country may reflect the degree to which research results are publicized as well as the level of research activity. Prior to introducing that material, however, it is helpful to give a broader indication of the issues involved by reviewing briefly the major research reports which characterize transgenic research. That is done below.

Research synopsis

MICROINJECTION: Habers et al. published one of the earlier (1981) successful accounts of the use of microinjection to create transgenic animals,

in that case mice. The researchers reported problems with regulating the expression of the inserted gene in the appropriate tissues. Stewart, Wagner and Mintz built on the Habers et al. research by studying the inheritability of the introduced genes. Again using mice as examples, they found those with the fully integrated B-Globin gene sequence transferred it in the Mendelian pattern - that is, with one adult carrying the trait one half the progeny on average will inherit the trait (p.1047).

LARGE ANIMALS: In preparation for work with large animals, Palmiter et al. evaluated the effects of potentially economic benefits from inserting rat growth hormone genes (rGH) into mice. The results were dramatic with some individuals exhibiting 1.8 fold weight gain (giantism) compared to the controls. The authors recognised, "The implicit possibility [of using] this technology to stimulate rapid growth of commercially valuable animals" (p. 614), with the economic benefits to come from a shorter production time and possibly increased efficiency of food utilization.

Hammer et al. reported the pioneering study on large animals by inserting successfully a cloned gene (rat or human growth hormone) in sheep, pigs and rabbits. These efforts indicated some of the differences with working with other than mice, especially as it involved locating the ova nuclei for microinjection (p. 683). The rates of success of injection were only modest - 12.8% for rabbits, 4.0% for pigs and 1.3% for sheep (p. 681), but the results were sufficiently efficient to show, "...the techniques have immediate application for both scientific and practical purposes" (p. 683).

LABORATORY ANIMALS: As just one example of the kinds of developments in that research area, Lacey, Alpert and Hanahan were able to infect horses, hamsters and one mouse strain with a gene causing fibroblastic tumors (p. 609). The recently patented mouse strain is another example.

PRODUCTION OF PHARMACEUTICALS: Gordon et al. were able to transfer to mice the murine whey acid protein gene and promoter so that the females expressed human tissue plasminogen activator (t-PA) in their milk. The protein t-PA has been used successfully to dissolve fibrin clots in blood vessels. This experiment indicated the potential of using transgenic farm animals to produce at a far lower cost specific proteins with pharmaceutical

applications in mammalian milk. It has been estimated that many currently scarce and expensive drugs could be produced by herds of 100 or so cows (Thompson).

From the material presented in Table 9, two general conclusions can be drawn. First, research is moving rapidly in this area and many potentially useful developments will be appearing over the next decade and beyond. Second, the U.S. is by no means the only player in this developing area. Indeed, the technological requirements are rather limited by scientific standards so that many less wealthy countries with a large trained scientific population can be expected to become active participants in the not-too-distant future. India is a prime example (Dr. Chakrabarty, personal communication).

The timing of the commercial availability of transgenic animals is conjectural at this time, but to some researchers, "It seems unlikely that appreciable numbers of transgenic animals will be produced before the year 2000" (Hansel, p.9). Particularly critical for many key developments is the ability to synchronize and control the activity of multiple genes. The commercial availability of such developments seems further away yet. Underlying these steps is the need to improve the efficiency and quantity of transferring genetic material into the ovum.

EXPECTED ECONOMIC IMPACTS

This discussion of expected economic impacts of animal patents is divided into impacts on inventors, impacts on users, and impacts on consumers (ultimate users). At this early date it is not possible to be definitive about how the economic impacts will play out in the marketplace. This analysis then is based on deductive analysis drawing on a knowledge of the structure and operations of the major sectors which are likely to be involved (see above).

Impacts on Inventors

When evaluating the potential impacts of animal patents on inventors, several classes can be characterized based on the form of propagation of the invention. That is, the ability of the animal to reproduce itself or not will have a major effect on the functioning and impacts of animal patents. This discussion, therefore, begins with a review of the inheritability issues and

Table 9: Examples of potentially patentable transgenic animals

A. United States

Development	Source of Invention	Comments	Source of Information
1. breast cancer-susceptible mouse strain	Medical School Harvard Univ.	1st animal patent-issued 4/12/88 Research supported by Dupont	Schneider, April 1988
2. Avian leukosis - resistant chickens	Dr. Crittenden, USDA ARS Poultry Lab	patent protection appears to have been applied for	DeQuattro
3. bovine GH in cows	Dr. First Univ. Wisconsin	sponsored by W.R. Grace Co.	Schwarze testimony, p. 330.
4. transgenic cattle for disease resistence, improved amino acid intake, & cloning	Grenada Corp. Houston, TX		Ellis,Senior VP, personal comm.
5. AIDS-susceptible mouse strain	several researchers believed to be actively involved	presently only humans and chimpanzees are susceptible, slowing research	Quimby, Cornell Vet. Coll., personal comm.
6. increased ovulation rates in livestock (FSH secretion)	several active programs		Hansel, p. 11

B. Other Countries

Development	Source of Invention	Comments	Source of Information
1. flounder with accelerated (1.4X) growth	Marine Research Inst. Nagasaki, Japan		Duffey
2. cattle and pig embryo production	Animal Biotechnology Cambrige Cambridge, UK		Nature, 328(1987):6
3. disease-resistant poultry	Transgenic Science, Inc. UK		Biotechnology Newswatch 8(1988):8

Table 9 cont.

4. mice producing HLA-B27 antigens	Holland	Nature 329(1987):447
5. transgenic trout with salmon GH	Japan	Biotechnology Newswatch 7(1987):8
6. interferon production in transgenic hamsters	Hayashibara Biochemical Labs., Japan	Mark letter, 14(1987):3
7. transgenic salmon with GH	UK	New Scientist 115(1987):42
8. transgenic sheep producing human blood clotting Factor IX and human alpha 1 antitrypsin in their milk	Scotland	Bio/Technology 6(1988):179
9. transgenic pigs with pGH	Australia	Bio/Technology 6(1988):14
10. engineered silkworm producing hepatitis vaccine	Japan	Duffey

their implications. From there the analysis focuses on the different inheritability and use classes of inventions and their meaning for inventors.

Inheritance Issues

Based on the material presented above, it can be concluded that, using available microinjection and retrovirus techniques for introducing genetic material into the ovum, the procedure is costly, tedious and, above all, inefficient. Until such a time as the efficiency of the process is improved many-fold, it will be less costly to propagate the invention by making the animal self-reproducible. This has been shown to be a scientific possibility. With self-reproducible higher animals, it requires far fewer animals if the trait is bred through the male side, the multiplication rate being far greater for males then females. Among the farm animals under consideration here, the female multiplication rate is greatest for poultry and least for cattle which typically produce but one calf a year. Production from a superior heifer can be enhanced many-fold through embryo transplant procedures, but that is costly.

Replication through the male line is not entirely satisfactory because, at best, only half the offspring will inherit the trait. This means some form of broadly available test procedure needs to be developed to determine which animals carry and do not carry the trait. This is a technical possibility and is not expected to be costly on a mass scale, but the system will take some time to develop. Inheritance of traits controlled by multiple genes, if it follows the expected Mendelian pattern, will be far lower, as low as five percent of progeny (Acker, Table 18-1).

Low inheritance rates may be tolerable among animals which are relatively valuable, or alternatively of low value but high multiplication rates. That is, it may be possible to breed through the male line relatively valuable laboratory animals, or poultry where the non-trait carrying chicks can be destroyed (as male laying chickens now are). For hogs and sheep, and especially the slow-reproducing cattle, this would not be feasible. Hence for the red meat species it appears essential the female too carry the trait so that it can be inherited at a relatively high rate. (As Mendel concluded, the offspring of parents who both carry a single gene-based trait will all inherit the characteristic). Achieving this goal is possible as females do inherit the trait, but the multiplication rate for disseminating the trait will take numerous generations, a lengthy process among slower-maturing species.

Propagating the trait through normal breeding procedures has two additional ramifications. First, it means the invention and the means to replicate it must be fully released to the market place. The inventor will have to rely largely on the protection provided through patents to recover a profit. Second, this procedure of disseminating the invention necessitates that the attribute is stably emplaced in the genome. To date, the stability of the transferred genes has not been tested over multiple generations, but there is no inherent reason to believe they should behave fundamentally differently from naturally-occurring genes.

From this discussion and the preceding material it is possible to describe four distinct Animal Classes as affected by patent legislation: 1) high-valued laboratory disease models and related animals, 2) high-valued animals used for producing pharmaceuticals, 3) low-valued but high reproducing animals (poultry) and 4) low-valued and low reproduction level animals (esp. cattle, but also sheep and hogs) (Table 10). Classes 1 - 3 may conceivably be propagated only by a male carrier of the trait, in which case the trait need not be stable across multiple generations. The biological characteristics of Class 4 make it an economic necessity that both males and females carry the trait so that it can be passed along to a large portion of the offspring. In all cases it will be necessary to develop a ready means of testing for the presence or lack of the trait in each individual. These factors give some insights into the role of patents and alternative intellectual property rights protection measures for each class of animals.

Alternative Forms of Protection

Patents are most effective in providing incentives for R&D investment if other forms of protecting an invention are not available, or feasible. Here, the role of patents and alternative means of preserving intellectual property rights for each of the four animal classes delineated above are described. Two alternatives to patents are considered. One is secrecy, the process of preventing users from determining how to replicate the invention. This may be done by keeping the process or formula secret (eg., comparable to Coca-Cola syrup), or by keeping the entire invention in-house. With corporate secrecy there are certain remedies which, under some circumstances, can be invoked if the secret is stolen, but public release of the means to recreate the invention is not among them (see eg., Bent, et al.).

A second alternative is the use of contracts (license agreements) which grant the inventor certain continuing rights following the sale. Thus, the inventor could demand the buyer agree to pay royalties following the sale as a condition for the sale. This arrangement would mimic an aspect of patent rights, but enforcement would be through contract law rather than under the Patent Act. Inventors would be responsible for drawing up the contracts, a possible special burden for small firms. More significantly, inventors interested in licensing would have to have a contract signed by prospective clients during negotiations or risk loosing the invention. Nonetheless, despite some practical complexities, it is important to recognize that effective intellectual property protection can be gained through alternative approaches to patents. Contracts may also be used in conjunction with patents to strengthen the rights of the inventor, or to clarify a point which is ambiguous under patent law. The suitability of secrecy, contracts and patents to Animal Classes 1-4 is described below.

CLASS 1 (disease models): Secrecy is not a viable alternative in this instance as the inventor will likely be called upon to provide both trait-carrying males and females to laboratories. The labs may require both sexes for experiments as well as needing to breed replacements. By providing to customers the means to replicate the invention the secrecy option is voided. Inheritance through the male line (eg., trait inherited by half the progeny) would seemingly be feasible as reproductive levels are high, at least for rodents, and the facilities for testing for the presence of the trait would be available.

It is probable that contracts could be used in place of patents (or possibly in conjunction). The number of laboratories, principally located in major medical research institutions, are limited in number and easily identified. The products are specialized with their differences readily revealed so that it would be difficult to sell, or even give away, examples without it being detected.

CLASS 2 (production of pharmaceuticals): This class of products appears to require relatively few individuals for the production of most products. Herds of but 100 cows have been mentioned as sufficient when the product is excreted in the milk. The use of hamsters or caterpillars would require a

greater number of individuals, but only a limited overall size seems necessary. As a result, the maintenance of the invention through secrecy, implying the animals be physically controlled by the inventor, seems a distinct possibility. Another form of secrecy could potentially be employed, that of making the trait non-inheritable through the animals released on the market. One means of achieving that would be to release only mosaic females which expressed the characteristic but could not pass it on (eg., the engineered genes were not in the germ line (egg)). Such a selection process would lead to the rejection of a large portion of the potential candidates, but the value of the animals could be such the cost of this approach would not be prohibitive.

Contracts are another alternative as the number of licensees would be small and hence relatively easy to monitor. With this number of alternative protection mechanisms, patent protection would seem to play a limited additional role.

CLASS 3 (poultry): Secrecy is not a viable approach with poultry as there are too many hatcheries which require males and females for the production of commercial birds. Contracting, nonetheless, appears viable and, indeed, has a precedent in the sector. The precedent is in the laying hen industry where breeders presently release breeding stock (parent and grandparent stock) to hatcheries for the production of commercial layers. These hatcheries are controlled by contract not to release the breeding stock, and a similar procedure could be used if the breeding stock carried an engineered gene. As producers use only females they could not propagate the strain. Inheritance through the male line only is feasible as the chicks are presently sexed at the hatchery and could be tested as well. Volume is such that the tests would have to be very economical to be feasible.

The broiler sector could operate similarly at the hatchery level, but contracts would be required to prevent diversion from production flocks using both males and females. Contract enforcement is made feasible by the limited number of integrators who dominate the business and control, through ownership of the birds, operations at the individual contract-producer (grower) level. It would be difficult, of course, to prevent growers from removing individual birds and reporting them in the mortality figures. But any sizable integrator receiving birds illegally from this source would almost surely be detected.

Within this system, patents seem to provide an administrative convenience but are not essential to the protection of R&D investments.

CLASS 4 (livestock): Livestock, consisting of the main red meat species, cattle, hogs and sheep, constitute the most complex case under patent law. They are relatively slow to reproduce, have a low net margin meaning the system cannot tolerate a process which increases costs substantially, and yet animals numbers are both numerous and scattered. This later factor means the only efficient means of dispersing a gene-based technology at this time is to make it inheritable through traditional breeding as carried out on most livestock farms. To be workable this would require the trait to be stable over generations.

Among dairy cattle it is possible the innovation could be dispersed through artificial insemination (AI), something presently done with half the U.S. herd. In the initial years, before the trait is established in the cows, but half the calves would inherit the trait. This would be a notable short-term economic problem if the trait were really cost-saving. AI is little used among the other livestock classes, and it would seem to require a very major cost-saving improvement to make the widespread use of AI feasible. Hence the trait can likely only be dispersed by providing both males and females with the trait and not permitting the females to mate with non-trait carrying males. This would create some management complexities and above all substantial delays in disseminating the innovation.

In terms of the incentive issue, the scenario described above virtually eliminates secrecy and contracting as alternative, general property protection mechanisms. Contracting appears implausible because of the very large number of farms involved, too many to be monitored effectively. However, it is conceivable contracting could be used with a small subset of farms, probably the larger ones and possibly those doing contract feeding. Thus, for this class, patents would seem to provide an important protection mechanism for recovering R&D investments in general sales.

Impacts on Incentives

From the above discussion, the incentive impact of patents for each class can be developed readily. It appears that Class 2 has strong alternative protection mechanisms available so the added incentive contributed by patents

would seem to be limited. Inventors of animals in Classes 1 and 3, with the possible alternative of contracting, would seem to benefit moderately from patents. Those working on Class 4 animals, however, would seem to get a high benefit from patent protection, although contracting is plausible if only a small number of large farms were selected to receive the animals. This material is summarized in Table 10.

It must be emphasized that, everything else held constant, small firms benefit more from patents than large ones due to the penchant of small firms to license technology and the impediment such firms face when attempting to enter production with limited capital and managerial reserves. Another proportionally large beneficiary from patents is universities. The patent agreements universities often have with researchers, as well as the Federal policy governing inventions made under Federal sponsorship, both specify patents over other forms of intellectual property protection. Hence, the ability to patent has a special incentive effect for universities (see Lesser, 1987 (b)).

Impacts on Users (Producers)

This sub-section treats the anticipated impacts of patented animals on users, many of whom will likely be livestock and poultry producers. As the impacts will vary across different forms of invention, it is convenient to structure the discussion along the lines of the animal classes discussed above (Table 10). That then is the order followed here. Due to the involved nature of agricultural production, and its large aggregates size, proportionally more space is dedicated to evaluating ramifications within the agricultural sector.

Class 1: Disease Models

Transgenic animal disease models serve a specialized function in an arcane area, that of medical research. Presently this sector uses numerous animal models; the option of patenting means that more are likely to become available through transgenic processes rather than sole reliance on spontaneous natural mutation. As a result of patenting, users may be required to pay a royalty on transgenic models or otherwise find reproduction rights are restricted. This will likely raise the cost of these models but otherwise not cause an administrative burden on a group already required to maintain detailed records as part of the scientific process.

Table 10: Classification of animals by impacts of patents

	Class 1 Disease Models	Class 2 Production of pharmaceuticals
Examples	mice, other lab animals	cows (in milk) hamsters, caterpillars
Economically feasible reproduction systems	male only possible	male only possible
Ramifications for technology	attribute may be relatively unstable as need not be passed across generations	attribute may be relatively unstable as need not be passed across generations
Testing for trait	yes - discard non-trait bearing animals	yes - discard non-trait bearing animals
Means of protecting investment	contracts patents	secrecy contracts, patents
Incentive impacts of patents	moderate	low

	Class 3 poultry	Class 4 livestock
Examples	chickens, turkeys	cattle, pigs, sheep
Economically feasible reproduction systems	male only possible	trait must be carried by both males and females, high inheritance rate
Ramifications for technology	intergeneration transfer not required	must transfer stably across multiple generations
Testing for trait	yes - discard non-trait carrying individuals	yes - non-trait-carrying will be fed and/or handled differently
Means of protecting investment	contracting possible, patents	contracting possible only with small number of large farms, patents
Incentive impacts of patents	moderate	high

The degree of cost increase will depend on a number of factors, including any stipulations of the enabling research funding, assuming that many of the new model inventions will be made by universities (as with the first mouse strain to receive a patent). Inventions made under Federal sponsorship, including from the NIH, will be affected by patent policy. The current law (37 CFR pt. 401 1986) permits universities and small firms to take title to inventions, the government reserving the rights of a royalty-free license and retaking the title in the interest of national security. Universities are now free to offer full-term exclusive licenses, thereby limiting the number of suppliers to one. If inventions made under Federal sponsorship are excessively priced that matter may be addressed through the Federal patent policy. Otherwise there is no clear indication patents will create major disruptions among the users of animal disease models.

Class 2: Animals Producing Pharmaceutical Products

Unlike the other invention classes discussed here, the production of pharmaceuticals in higher animals is a new industry. As such, there is no existing structure to interact with and potentially displace. The consideration of impacts on users takes a different connotation in this instance.

The production of pharmaceuticals by cows, hamsters and so on seems most likely to be done in-house or under contract by an established pharmaceutical company or by a small, new firm (which might contract with an established company to market the product). Under these arrangements a patent would not be essential and might not be sought. Overall the existence of patents would appear to have no major impact on users.

Classes 3 and 4: Poultry and Livestock

Before it is possible to discuss in detail the implications of patents in this sector, it is important to understand the economic implications of potential developments for each of the major species. This is necessary because of any price or cost implications for a group of products which compete more or less directly among themselves for consumers' food dollars. In the absence of data on how patented animals will perform in the field, it is necessary to infer the results from related technologies. Relevant research results are summarized in Table 11.

Table 11: Impacts of biotechnology products on livestock production costs

Species/Class	Product	Projected Impacts	References
Dairy Cows	Injected Somatotropin (growth hormone)	6-25% increase in production. 5-26% return at current prices. potential 20% reduction farm numbers; scale neutral	Kalter, et al. OTA 1986
Hogs	Injected Somatotropin	Gain efficiency +10%, backfat -32% production costs -8.5%	Shagam. Kalter and Milligan
Cattle	Injected Somatotropin	Gain efficiency +21% production costs -7%	Kalter and Milligan
Poultry	Disease Resistance	Savings from Marek's disease $178.4 million (2% costs)	in Acker

Moving from the information above to projections of the impacts of transgenic animals requires several assumptions regarding economic relationships. These are laid out in Table 12.

Table 12: Economics relationships applying to the anticipated impacts of patents on livestock production.

Assumption/Relationship	Reference
A. Products from transgenic animals acceptable to consumers	---
B. In longer term near universal adoption of major cost-saving technology is mandated by competitive conditions	---
C. Long term savings will be passed along to consumers in form of lower prices	---
D. Impacts will be seen more in changes in market share than in total meat consumption increase	Ikerd 1982
E. Demand is inelastic, meaning a decline in price leads to a less-than-proportional increase in sales	Estimates in Tomek and Robinson
F. Cross-demand elasticities are asymmetric meaning beef and pork are potential gainers and poultry losers	Ikerd 1987

ROYALTY COLLECTION AND STRUCTURE: For Class 3 and 4 animals it can be expected that the patent holders will demand royalties from users. Certainly

they have the legal right to do so. Collection will be a complex process (see further discussion immediately below) but with the high cost of animal development in this area, it seems inconceivable that the entire investment can be recovered from the initial sale, or from the sale of the first generation. Yet once released in a self-perpetuating form, the invention effectively enters the public domain unless an effort is made to collect royalties. Unlike seeds, the purchaser has little need to return to the original source for additional purchases (see discussion in Lesser, 1986).

Royalty collection would not seem to be a complex arrangement for poultry. With broilers there are relatively few integrators who have title to the birds. The genetically engineered chickens could be sold to the integrators' hatchery operations where pullets are produced. Supervising these few, large, easily identified operations would be relatively easy. Egg operations are somewhat more complex as there are a greater number of primary customers. The industry, nonetheless, operates through a relatively small number of hatcheries which may be owned by a large integrated operation, or independent suppliers to smaller producers. In either case the number of customers seems small enough to be tractable in a royalty-collection arrangement. The existing breeders are likely to become involved with any patented poultry, if not as owners of the patents, then as incorporators of the trait into production birds and distribution of parent and grandparent stock to hatcheries.

Patented animals involving royalty collection would also seem to fit relatively easily within the structure of the pork sector. Large farrow-to-finish operations are largely self-contained, buying in small numbers of breeding animals and shipping market hogs. On a contract production basis, or other contractual arrangement, it would appear tractable to collect royalties for, say, all animals shipped to packers. Further stipulations could restrict sales to packers only, reducing the possibility of improper diversion Existing large hog breeders would likely become involved in the commercialization, multiplication, and distribution of patented pigs so no major change in that sector should be anticipated.

What will be affected is smaller operations, especially those specializing in feeder pig production or finishing. These operations will be far more difficult for the patent holder to monitor, and, with an increasing amount of production done by very large operations, there will be a tendency

to provide patented animals only to the larger operations. The existence of animal patents could then accelerate the current trend to concentration in pork production. Size economies are such there seems little likelihood the number of operations will reach a critically small level, but the role of "family farms" in this sector could be reduced.

Far more complex to anticipate is the incorporation of royalty collection into the beef and dairy cattle sectors (see also Lesser, 1987(a)). Calving throughout the year on numerous farms would make royalty collection an extremely difficult, and expensive, process in the dairy sector. Similarly difficult would be the control of the disposition of surplus trait-carrying animals which could be diverted to breeding and hence cause a partial loss of control over the invention. Programs in the recent past have attempted to specify that surplus cows go only to slaughter (see eg., Kaiser and Novakovic), but the male calves, which move through multiple hands, would be far more complex to track.

Even more involved is the incorporation of royalty collection into the beef sector. The separation of calf production and cattle feeding, the numerous producers and the myriad of breeds involved all act to make monitoring a monumental problem. Breeding, similarly, is done on a dispersed basis so there is no firm with a national or even regional dominance with which to collaborate on distribution and royalty collection.

At this early stage it appears patented cattle will involve some fundamental change in the structure and organization of the beef and dairy sectors if royalties are to be collected. With beef cattle, for example, the patent owner may enter (by ownership or contract) feeder calf production, selling the castrated steer calves to independent feeders but have the heifers fed by custom operators, allowing the retention of ownership and control. The workings of a new organization in dairying is unclear at this time, unless it involves a growth in the presently very small number of 2,000-plus head herds. The sheep sector shares many characteristics with cattle, except that being far smaller it is potentially easier to adjust.

Whatever the eventual arrangement, it appears to entail a far greater structural change than will be needed for poultry and hogs. This will be an expensive and time consuming process. Because of this, an economically-viable development in cattle would seem to have to provide a far greater efficiency improvement than will be needed in poultry or hogs. This is a problematic

situation as cattle are biologically the least efficient converters and, from a price competition perspective, the most in need of cost-reducing technological change.

PRICES: There is little reason to believe livestock producers will pay "too much" for patented animals. For them, the selection decision is an economic choice. If the trait reduces costs by a dollar a pound, then the farmer should pay up to (but no more than) the equivalent of a dollar a pound more for the patented animal. At prices above that level, it is more profitable to choose the non-patented alternative. Thus, as long as the traditional breeds remain available, they provide an absolute cap on how much can be charged for the patented alternatives. The continued existence of traditional breeds seems in question for only poultry where the pure stock is closely held by a few firms (see Abplanalp).

There is some evidence that farmers will at most pay substantially less than the savings associated with an innovation. Considering improved seed varieties, Butler and Marion cite some evidence suggesting, "... that farmers are willing to pay a premium that is much lower than is justified." (p. 61). Among other sources they cite a Pioneer Hi-bred study showing for the period 1970-81 that farmers' gross income rose by 3.2 times the increase in seed corn prices. Dr. Hardy, (President, Boyce Thompson Inst., personal communication) too, finds plant-based productivity improvements can be priced at but 25 to 50 cents per dollar of expected return. If livestock farmers act in a similar way, the ceiling on viable price increases for patented animals will be far below cost savings.

Summary

Little impact is expected on the laboratory animal (Class 1) sector. In part this conclusion can be reached because much of the research in this area is government supported giving Federal authorities considerable leverage in the eventual dispensation of patented animals in this group. Class 2 animals will likely be incorporated into the large pharmaceutical sector with little apparent change.

Within livestock, Class 4 producers (red meats) stand to benefit relative to Class 3 operators (poultry) from transgenic animals if current research progresses as expected. In all cases for which preliminary information

exists, the efficiency gains are expected to be sufficiently large that eventual near-universal adoption can be expected if the animals are made available at non-prohibitive prices. Without these forms of innovation, there are indications that red meat will continue to loose share to poultry. Thus, red meat producers can be expected to be general gainers and poultry producers general losers from transgenics, but that implication could change as research progresses. Red meats may also benefit in consumer acceptance from a lower-fat product, but that factor cannot be predicted at this time.

In terms of the number and size of production operations, there is nothing inherent about these developments which would seem to affect poultry and red meat operations in the aggregate. Less feed per head will be required, but essentially the same number of animals will be needed. The exception is dairy for which production per cow is expected to increase, but with no concomitant increase in consumption predictable from lower prices, the size of the sector can be expected to shrink. Early projections call for reductions in farm numbers in the range of 20 percent.

When the royalty collection process is considered the structural ramifications change. For Class 1 and 2 animals royalty collection does not appear to be a major factor. Similarly, royalty collection would seem to be accommodatable within the poultry and pork sectors, although with some tendency to concentrate on larger operations and thereby possibly accelerating the trend to fewer, larger producers (and fewer "family farms") in the pork sector. No major impact on the breeding sectors are foreseen.

Indications at this time are that the collection of royalties will require a major reorganization in the dairy and beef cattle subsector (including breeding). The eventual form this might take is unclear at this time, but for beef it could operate in concert with current efforts to produce more standardized cattle as a market requirement. This will be a lengthy, expensive process which will probably delay the widespread introduction of patented cattle until a major cost-saving innovation is available which will justify the necessary costs. As cattle are relatively inefficient converters of feed, this sector in the medium term could lose some competitive advantage to poultry and pork.

Impacts on Consumers

Anticipated impacts on consumers are described by animal class.

Class 1: Laboratory Animals

Much exciting work is currently underway on the development of new disease models for medical research. Implications at this time are that real advances in the improvement of human and animal health, and in the broader realm, the understanding of the regulation of major biological systems, could come from this work. Certainly that would follow if a rodent strain susceptible to AIDS, currently a matter of much attention, were developed.

The cost impact of patented animals is likely to be a small part of the total cost of health care. This is especially true as much of the development work is underwritten by Federal research grants. As the research nears commercialization, increased activity by private firms can be anticipated. In terms of final costs, if the models developed are less costly than current experimental procedures, or lead to more effective treatment/prevention, then the net effect could be lower costs for individuals.

Class 2: Production of Pharmaceuticals

Current work on the use of animals to produce proteins with pharmaceutical uses appears to be directed to finding more economical means of providing currently-available products. As such the cost effect on consumers should be downward. There is no reason to believe the existence of these products will make the pharmaceutical sector any more concentrated, and they could facilitate the entrance of new firms. Thus, consumers would seem to benefit by the introduction of these new production techniques.

Class 3 and 4: Poultry and Livestock

At the present time, the poultry and livestock sectors operate as competitive industries. In such cases, the benefits to cost-reducing technological developments will be passed along to consumers in the long term. Any benefits to producers will accrue to early adopters. Consumers then have an excellent prospect of benefiting from the forms of development likely to lead to patented poultry and livestock. The point of uncertainty is the potential for patented animals to contribute to a process which would make these sectors non-competitive. Certainly some components of these sectors have been moving in that direction, and the introduction of patented animals could potentially contribute to that process.

The literature on this subject suggests that R&D in itself does not lead to inordinate concentration levels. Two factors, and two theories to explain those factors, pull in opposite directions on firms, the need for small firms

to innovate to survive and the difficulty for large firms to remain highly innovative risk takers. The empirical evidence shows that these forces balance each other when the industry four-firm concentration level reaches 45 to 50 percent (literature review in Lesser and Masson, Chaps. 3 and 4). These are not levels which cause widespread alarm among economists.

Experiences under the Plant Variety Protection Act (PVPA), the closest comparable situation to patented animals for which detailed economic analyses have been conducted, provide useful insights. Butler and Marion, in a study carried out from the U.S. Department of Agriculture, found no clear connection between much merger activity with seed breeders and the existence of the PVPA. Nor did the resultant price increases appear unwarranted or unreasonable.

The basic structure and biological situation in the livestock and poultry sectors is fundamentally different from seeds, and the outcome could be considerably different. However, the available information on size economies in broiler integration and livestock feeding suggest little opportunity for a very few firms to dominate this sector. The chronic low profits in agriculture in general, and livestock in particular, have discouraged the entry by large firms. If anything, firms like Oscar Mayer have moved further away from production agriculture. Therefore, there seems little basis for concern that the production process will become unduly concentrated for the foreseeable future.

Remaining potentially problematic are the packing sector and breeding for hogs and poultry. These are presently relatively concentrated; further concentration would be a cause for concern. Much recent concentration increase in meat packing, which was unaffected by animal patents, is attributable to mergers. Mergers are subject to the control of antitrust law, which seems the appropriate place to address this matter. Breeding is a different matter as much of the position of the leading poultry and swine firms is based on ownership of pure lines. This entry barrier cannot be controlled legally; rather the preferred approach would seem to be the maintenance of a competitive industry, to which the public sector makes a major contribution. If steps are followed to maintain a competitive livestock and poultry sector, then consumers can be assured of major benefits from research leading to patented animals.

CONCLUSIONS

Economic Considerations

Past requirements by the Patent Office suggest strongly that only inventions which depart in some major way from the state of the art will be granted patents. Among higher animals the area of application which seems most likely to qualify is the products of genetic engineering. Some products of traditional breeding may also be patentable. Although this work with regard to higher animals is in its infancy, with the earliest substantial success reported only in the early 1980's, many exciting developments are presently underway. The first to receive a patent, a transgenic mouse susceptible of contracting breast cancer, is such a development. Other related work has the potential of speeding up the understanding of human and animal diseases, and of controlling/preventing them. The procedures under study could one day be applied to preventing birth defects. In a related area, prospects appear good for lowering the production costs of some proteins with pharmaceutical applications by having them secreted in mammalian milk.

Research on transgenic farm animals has taken a different course with an emphasis on improving feed conversion efficiency, disease resistance, and similar economic characteristics. Results achieved in experimental trials using related but non-transgenic procedures suggest the potential efficiency gains to be made in this area of application are substantial. Feed conversion efficiency gains in the range of 20 percent have been reported, with the meat leaner and potentially more acceptable to health-conscious consumers. The commercialization of these developments appears to be lagging behind laboratory animals due in part to the very low success rate with gene transfers, the slower reproduction cycle of larger animals, and other biological, economic and regulatory factors.

To date, much research on transgenic animals in the U.S. is being done at universities and other publicly-supported research facilities. The private sector will probably increase its level of activity when developments come closer to the commercialization stage. Substantial activity has already been reported overseas, especially in Japan.

Incentives With Patents

Incentives for investment in transgenic animals come in part from the ability under the patent system to exclude others from unauthorized copying.

This is a particularly acute matter for patented animals as many will inherit the ability to reproduce themselves, including the novel trait for which the patent was granted. Thus, with animals, the purchaser acquires not only the product but the means of reproducing it. With many seeds, which share a similar self-reproducibility attribute, experience has shown there was little private investment without the option to exclude direct copying. This pattern seems to apply to animals so that a lack of patent protection would provide a substantial disincentive for R&D investment. That said, the degree of incentive with patents will vary, depending on some economic and structural characteristics of the particular industry where the product is to be used.

As a generalization, patents would appear to provide a moderate level of incentive for laboratory animals and poultry. This is because the structure and operation of these sectors is such that contracts could be used in place of patents. In contrast, the degree of incentive for research on livestock would be expected to be far greater because contracting, and the other protection option, secrecy, would not be feasible on a broad scale. At the other extreme, developments in animals capable of producing pharmaceuticals can be anticipated to have little reliance on the patent system.

If the ability to exclude others from unauthorized copying is a major benefit of patenting, it also creates the major complexity for users. This refers to the procedure for collecting royalties for progeny, a need which in this analyst's judgment is essential given the low profitability of agriculture and the consequential requirement to spread the return to R&D over time. Royalty collection may be accommodated with relative ease within the vertically and horizontally integrated poultry and swine systems. For the dispersed beef and dairy cattle sectors the complexity will be great and may necessitate a significant restructuring of the industry. Some increase in the erosion of numbers of "family farms" can be expected as a result.

Benefits to Producers and Consumers

Consumers are clear, if indirect, beneficiaries of advancements in health care. The benefits may come through a better quality of life, lower costs, or both. The production of pharmaceuticals fits within the definition of health care. No major costs to users of these animals (eg., researchers) is anticipated.

Producers of livestock and poultry products should benefit from reduced production costs, although in the longer term monetary benefits will be passed

along to consumers in the form of lower prices. Lasting benefits will be in the form of relative shifts between, and within, red meats and poultry. Current research results appear to benefit red meats most, which could help to slow an apparent cost and price preference change in favor of poultry. These conclusions are contingent on the expectation that the livestock and poultry sectors will remain competitive. The sub-components requiring the greatest attention are hog and poultry breeding, and beef packing as the number of firms continues to decline. Producers have little likelihood of paying "too much" for patented animals as long as traditional breeds remain available as competition to patented varieties.

Consumers should see the price of meat and livestock products fall as more efficient animals enter the sector. Total consumption of these products on a per capita basis will be largely unaffected, unless the product characteristics are fundamentally changed, but the shares of the several competing products may change.

Disincentives Without Patents

The implications of <u>not</u> allowing patents for animals have been suggested but not fully explained. This is a speculative activity, but insights can be gained by examining the role of alternative means of protecting R&D investments. Pharmaceutical products (Class 2) could be protected through secrecy so that patents are seemingly not necessary. Laboratory animals (Class 1) could be protected through contracts so that patents are not essential. The added administrative cost and complexity could nonetheless slow investment, possibly delaying research results.

Much of the poultry sector (Class 3) is sufficiently concentrated so that control through contract is plausible, if complex. Smaller operations, especially in egg production, would likely find access to the patented animals limited, which would accelerate concentration in the sector. This would have social and regional economic implications but aggregate concentration is unlikely to become great enough to be of general concern. Secrecy is not a plausible alternative. Presently with firms sharing similar technologies and management proactives, secrecy is nearly impossible to maintain, a point emphasized by the high turnover of managers even in major firms like Purdue Farms.

Red meats (Class 4) would be most disadvantaged by the inability to patent animals. With dairy and beef cattle any alternative protection scheme would be highly cumbersome and complex, minimizing the potential to recover R&D investment. Research on these species would then be lower than otherwise, leading to both higher meat prices and a greater shift to poultry. Within the red meats, beef, with its complex and dispersed production system, would be impacted most and hogs least. The lack of patented hogs would likely contribute to a more rapid concentration in large confinement operations where contracts control could be used and a concomitant reduction in smaller farms.

Summary Appraisal

Overall, current research on transgenic animals holds the promise for substantial public benefit in two key areas, health care and food prices. The ability to patent these developments will provide important additional incentives to R&D investment, but the role of patents should not be overstated.

Costs will likely be borne by some intermediate-sized livestock producers, too small to participate with patented animals, too large to operate in specialized market niches. Especially vulnerable are the beef and dairy cattle sectors. In this way, patents may add to the economic forces for change and greater coordination already underway in the sector. These are substantial matters, but not of the magnitude predicted by some observers (eg., Doyle testimony).

Policy Considerations

Within the broad area of patent law there are many subordinate policy choices to deciding whether or not to allow higher animals as patentable subject matter. Three of those issues are discussed here, royalty collection, deposits, and the research exemption.

ROYALTIES: The collection of royalties is one of the confounding issues of animal patents, and the major motivator of the anticipated structural change discussed above. To avoid these potential problems, some observers (see eg., Merges testimony) of the system have proposed an exemption be allowed following the pattern of the Plant Variety Protection Act (see above). This is also the position adopted by the National Cattlemen's Association.

The option to require royalties is one of the key components of patent protection. To remove it is to weaken greatly the incentives to invest in R&D. Resultant investment levels could be substantially sub-optimal or, alternatively, inventors may choose to bypass the patent system in favor of secrecy or contracts. With farm animals that would almost certainly mean limiting release to a select number of large breeders and feeders. Such an approach would likely be less efficient than the allowance of market forces to reshape the industry, and would inhibit access to an important new cost-reducing technology by small and medium sized operations no matter how well managed.

For these reasons the allowance of a farmer exemption is not recommended.

DEPOSITS: Current technology and past Patent Office practices combine to suggest that deposits of patented animals may be required in many instances. The Patent and Trademark Office should rethink official policy on this matter and, if deposits will indeed be needed, initiate the development and evaluation of a policy in the near future.

RESEARCH EXEMPTION: While the recommendation is made here not to grant a farmers exemption, the opposite position is taken in the research exemption issue. A broad and clear policy allowing research use on patented animals seems absolutely necessary for the orderly progress of research, and reasonable limit of private economic power, in this product area. At this time the scope of the research exemption remains unclear for this (and other) products. This matter needs to be clarified through changes in the patent legislation if not otherwise. (For a discussion of the research exemption issue see Bent, et al., Merges, or Tegtmeyer).

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